

U.S. Pat. App. Ser. No: 09/461,829

Page 3

III. At page 4 of the Office Action, claims 1-4, have been rejected under 35 USC §102(b) as being anticipated by McGuire '669.

The Examiner states that '669 discloses replacement ligaments where sutures are attached prior to implantation. In view of the amendment to claim 1, this rejection is respectfully overcome. Claim 1 requires that the replacement ligament has sutures attached prior to preservation and packaging of the ligament having attached sutures. '669 does not teach or suggest a replacement ligament which has sutures attached prior to preservation and packaging. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. At page 3 of the Office Action, claims 35, 36, and 38 have been rejected under 35 USC §102(b) as being anticipated by or in the alternative, under 35 USC §103 as obvious over McGuire '669.

Regarding the rejection under section 102, the Examiner states that '669 meets the limitations of the claims because '669 teach that the sutures are pre-attached prior to surgery. Claim 35 has been amended to clarify that the sutures are attached to the replacement ligament prior to sterilization and packaging of the ligament/suture unit. In view of the amendment to claim 35, it is submitted that '669 does not teach each and every element of the claimed invention as required for anticipation under 35 USC §102. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Regarding the rejection of the claims under section 103, the Examiner states that it would have been obvious to one of ordinary skill in the art to have pre-attached sutures as taught by Dumican et al. with the graft ligament of McGuire in order to save time in the surgery. A brief analysis of Dumican et al. is set forth below.

Dumican et al. disclose prosthetic vascular grafts and connective tissue grafts composed of absorbable and non-absorbable polymers. The Examiner states that Dumican et al. teach ligament grafts having pre-attached sutures, where the graft is packaged and sterilized. This teaching is not found. Dumican et al. describe a connective tissue repair device having a 10-100 % absorbable component and the remainder of the device, if any is a non-absorbable component. Dumican et al. go on to describe specific co-polymers, composition of warp yarns of the braid, and texturization and

U.S. Pat. App. Ser. No: 09/461,829

Page 4

heat treatment of the braid. Examples 1-6 are directed to a vascular graft and examples 7-13 are directed to a connective tissue graft. Neither the specification, claims, nor examples, teach a connective tissue graft having pre-attached sutures. Rather, the specification generally disclosed that suitable co-polymer materials include polymers used in sutures. It is noted that example 4 discloses that after the vascular graft is knitted, it is treated and helically wrapped with monofilament suture material which is attached to the surface of the graft using an adhesive. This simply says that the vascular graft is wrapped with monofilament suture, not that the synthetic graft has pre-attached sutures. Further, the connective graft examples do not recite this.

McGuire '669 does not suggest the presently claimed graft having pre-attached sutures. Dumican et al. do not cure the deficiencies of McGuire '699 because Dumican et al. do not teach or suggest a connective tissue graft having pre-attached sutures.

In view of the amendments to the claims, and the arguments set forth above, it is submitted that the invention is unobvious in view of McGuire and Dumican et al., taken alone or together. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

V. At page 6 of the Office Action, claims 5, 6, and 39, have been rejected under 35 USC §103 as being unpatentable over McGuire in view of Schmieding.

The Examiner states that it would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place. In view of the following, this rejection is respectfully traversed.

The claims as amended, require a graft replacement having pre-attached sutures to form a graft unit, where the unit is preserved and packaged. McGuire does not teach a graft replacement having pre-attached sutures to form a graft unit, where the unit is preserved and packaged. Schmieding does not cure the deficiencies of McGuire because Schmieding also does not teach or suggest the presently claimed graft replacement having pre-attached sutures to form a graft unit, where the unit is preserved and packaged.

U.S. Pat. App. Ser. No: 09/461,829

Page 5

In view of the amendments to the claims, and the arguments set forth above, it is submitted that the invention is unobvious in view of McGuire and Schmieding, taken alone or together. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

It is submitted that claims 1-6, 35, 36, 38, and 39, are in condition for immediate allowance and early notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at her Spotsylvania, Virginia telephone number on any questions that may arise.

Respectfully submitted,
LIFENET



Susanne M. Hopkins
Attorney for Applicant
Registration no: 33,247

Date: July 16, 2002

LIFENET
5809 Ward Court
Virginia Beach, Virginia 23455
Phone: (540) 834-0000

U.S. Pat. App. Ser. No: 09/461,829
Page 6

ATTACHMENT A

Please amend the below claims as set forth.

Claim 1 (Amended). 1. A replacement package for the repair of a damaged ligament, comprising:
a graft comprising a non-autologous graft material having a proximal end and a distal end,
a first set of sutures attached to the proximal end, and a second set of sutures attached to the distal
end, to form a graft unit having pre-attached sutures,

wherein [the graft] said graft unit having pre-attached sutures is preserved and provided in
sterile packaging.

Claim 35 (Amended). A kit for replacing a damaged ligament in a patient comprising a sterile
packaged prepared non-autologous replacement ligament said ligament having pre-attached sutures
to form a graft unit for aiding in insertion into a patient, and a graft fixation device, said graft unit
comprising attached sutures.